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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 09/862,571      | 05/21/2001  | Glenn McGall         | 2719.2019-001       | 9482             |

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| EXAMINER |
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BORIN, MICHAEL L

| ART UNIT | PAPER NUMBER |
|----------|--------------|
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1631

12

DATE MAILED: 08/07/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/862,571

Applicant(s)

MCGALL ET AL.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 1-12 is/are pending in the application.
- 4a) Of the above claim(s) 4,5,8,10 and 11 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) 1-3,6,7,9,12 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_.

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## **DETAILED ACTION**

### ***Status of Claims***

1. Amendment filed 06/02/2003 is acknowledged. Claims 13-42 are canceled. Claims 1-12 are pending. Claims 4,5,8, 10,11 remain withdrawn from consideration.

Claims 1-3,6,7,9,12 are addressed to the extent they read on the elected species.

It is noted that claim 1 is amended to recite "polyanionic chain" so that, as explained by applicant, "claims 10, 11 are properly dependent on claim 1". Applicant is reminded that claims 10, 11 are withdrawn from consideration as being drawn to a non-elected groups. Amendment of claim 1 to remove the non-elected subject matter is requested.

Rejections and/or objections not reiterated from previous Office actions are hereby withdrawn. The following rejections constitute the complete set presently being applied to the instant application.

### ***Claim Rejections - 35 USC § 112, second paragraph.***

2. Claims 1-3,6,7,9,12 remain rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is made for the reasons

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set forth in part (B) of paragraph #4 of the preceding Office action and further in view of the following.

Applicant argues that it is well known in the art that phosphoramidates can "readily be reacted to form phosphate groups". Phosphoramidates do not convert to phosphates spontaneously; they are capable of being converted by a string of specific chemical transformations. In support, applicant submit excerpts from "Biochemistry" textbook which show use of phosphoramidates in synthesis of polynucleotides. In the referenced text, however, the phosphoramidated nucleotides further interact with another nucleotide derivatives, and then the phospho-moiety is being sandwiched between two bases before getting oxidated. In contrast, the instant claims require that phosphoramidate is being added as a terminal group to an existing unprotected nucleotide. The references do not address such conversion, nor it is described in the specification. In addition, the lack of support in either specification or prior art brings up lack of written description consideration.

***Claim Rejections - 35 USC § 112, first paragraph.***

4. Claims 1-3,6,7,9,12 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for reducing non-specific binding of a particular protein (fluorescent protein conjugate phycoeretrin-streptavidin), does not reasonably provide enablement for reducing non-specific binding of any unspecified molecule.

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The rejection is maintained for the reasons of record and further in view of the following.

Applicant argues that the fact that negative charge of nucleic acids does not preclude specific binding to the nucleic acids proves that an increase in the negative charge will not increase non-specific binding of positively charged molecules. Examiner disagrees. The discussion of specific binding is unrelated to binding which occurs non specifically, e.g., by attraction of negative and positive charges. Therefore, Examiner maintains that the addition of a negatively charged phosphate group will more likely increase non-specific binding of positively charged background molecules, rather than decrease as intended by the claimed method.

Further, applicant argues that the claims method involves "relatively small" number of additional charges. The degree by which additional charges being alter the overall charge of nucleic acid is not defined in the claims. Thus, Examiner disagrees that claims 6-9 recite adding just a single negatively charge phosphate to an oligonucleotide of 2-120 units: First, claim 6 recites "at least" one; second, in the case of 2 nucleotides in a molecule, addition of a negative charged moiety doubles its negative charge.

"When Examiner sets forth reasonable grounds in support of his conclusion that the claims may be read on inoperative subject matter, it becomes incumbent upon applicant either to reasonably limit claims to approximate area where operativeness

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has not been challenged or to rebut examiner's challenge by submission of representative evidence or by persuasive argument based on known laws of physics or chemistry". *In re Cook and Merigold, 169 USPQ 298 (CCPA 1971)*.

Applicant further speculate (last paragraph on p. 9) that replacement of protective groups with a negatively charged phosphate moiety would reduce non-specific binding because presence of protective groups can induce non-specific binding by hydrophobic or negatively charged moieties. This argument seems more like justification for an obviousness rejection that alleviation of examiner's concerns about the scope of enablement.

4. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

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5. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to 5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

MICHAEL BORIN, PH.D  
PRIMARY EXAMINER

July 31, 2003

mlb

A handwritten signature in black ink, appearing to read 'Michael Borin', is written over the printed name and title.